



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,280	09/30/2002	Jeffrey C. Leung	013341.000019	5694
24239 7590 04/02/2007 MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709			EXAMINER DOWE, KATHERINE MARIE	
			ART UNIT 3734	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/065,280

Applicant(s)

LEUNG ET AL.

Examiner

Katherine M. Dowe

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/16/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Allowability Withdrawn

1. The following is a complete response to the amendment after notice of allowance and newly submitted Information Disclosure Statement filed 2/16/2006. The newly proposed claims, 31-98, will not be examined because they were proposed after prosecution was closed and they raise new issues. The Notice of Allowability sent 11/17/2005 is withdrawn due to the reference, McKenzie (GB 1,091,282), submitted in the IDS filed 2/16/2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 10, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by McKenzie (GB 1,091,282). Regarding claims 1 and 10, McKenzie discloses a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, In 128 – pg 4, In 9). Furthermore, by forming the barbs in such a way, the barbs also have an overlapping disposition (Fig 11). In the overlapping disposition, part of the underside

Art Unit: 3734

of one barb is derived from part of the topside of an adjacent barb since the barbs are formed from the same monofilament suture thread (pg 3, ln 128 – pg 4, ln 9).

Regarding claims 2 and 26, McKenzie further discloses the barbs may face in only one direction (Fig 6; pg 3, ln 48-51).

Regarding claims 3 and 27, McKenzie further discloses the suture may have a first barbed portion (35) that faces toward a first end (38) and a second barbed portion (36) that faces toward a second end (39) (Fig 9; pg 3, ln 103-109).

Regarding claims 16 and 25, McKenzie further discloses the ratio of the barb cut distance to the suture diameter is about 0.1-6 as shown in Fig 11. Additionally, the barbs are staggered along the length of the suture as shown in Fig 11.

Regarding claims 12, 14, 17, and 19, McKenzie discloses the suture may be made from a non-absorbable material, such as plastics or metals (pg 4, ln 40-46).

Regarding claims 11, 28, 29, and 30, McKenzie discloses the barb cut length of an overlapped barb is greater than the barb cut distance between adjacent barbs as shown in Fig 11.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3734

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282). McKenzie discloses the invention substantially as claimed including a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128 – pg 4, ln 9). Furthermore, by forming the barbs in such a way, the barbs also have an overlapping disposition (Fig 11). The ratio of the barb cut distance to the suture diameter is about 0.1-6 as shown in Fig 11. Additionally, the barbs are staggered along the length of the suture as shown in Fig 11. However, McKenzie does not disclose the specific dimensions of the radial spacing of the barbs in the staggered disposition. Applicant has not disclosed that having the barbs radially spaced specifically at 180 degrees or 120 degrees solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the barbs radially spaced at any angle such that a staggered disposition is obtained. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the barbs were radially spaced at 180 degrees or 120 degrees because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie.
6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282). McKenzie discloses the invention substantially as claimed including a

Art Unit: 3734

barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128 – pg 4, ln 9).

However, McKenzie does not disclose the specific number of times the suture is twisted per inch. Applicant has not disclosed that having the suture twisted specifically 2 to 17 times per inch solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture twisted. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the suture was twisted 2 to 17 times per inch because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie.

7. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282). McKenzie discloses the invention substantially as claimed including a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128 – pg 4, ln 9). However, McKenzie does not disclose the specific dimensions of the spirality angle. Applicant has not disclosed that having the suture with a specific spirality angle of 12-18 degrees solves any stated problem or is for any particular

Art Unit: 3734

purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture having any spirality angle.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that suture had a spirality angle of 12-18 degrees because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie.

8. Claims 13, 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282), as applied to claims 1 and 16 above, in view of Branch (US 5,520,691). McKenzie discloses the invention substantially as claimed, however he does not disclose the suture may be bioabsorbable. Branch discloses a similar barbed suture that may be formed from an inert material such as nylon, as discussed by McKenzie, if the connection is desired to be permanent. Alternatively, the suture may be formed from a bioabsorbable material including polydioxanone if the connection is desired to be temporary (col 6, ln 28-33). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the barbed suture of McKenzie et al. such that it was formed from polydioxanone instead of nylon such that the suture may be bioabsorbable. Thus, the suture may be absorbed by the body at the end of its useful life and a second surgery would not be necessary to remove the sutures at a later time.

9. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie (GB 1,091,282). McKenzie discloses the invention substantially as claimed

Art Unit: 3734

including a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128 – pg 4, ln 9). Furthermore, by forming the barbs in such a way, the barbs also have an overlapping disposition (Fig 11). The ratio of the barb cut distance to the suture diameter is about 0.1-6 as shown in Fig 11. Additionally, the barbs are staggered along the length of the suture as shown in Fig 11. However, McKenzie does not disclose the specific dimensions of the barb cut angle and the spirality angle or the ratio of the barb cut depth to the suture diameter and the ratio of the barb cut length to the suture diameter. Applicant has not disclosed that having the suture with a specific spirality angle of 12-18 degrees, a specific barb cut angle of 140-175 degrees, a specific ratio of barb cut depth to suture diameter of 0.05-0.6, or a specific ratio of barb cut length to suture diameter of 0.2-2 solves any stated problem or is for any particular purpose. Moreover it appears that the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture having any appropriate dimension. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the suture had a spirality angle of 12-18 degrees, a barb cut angle of 140-175 degrees, a ratio of barb cut depth to suture diameter of 0.05-0.6, and a ratio of barb cut length to suture diameter of 0.2-2 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie.

Conclusion

10. Applicant's submission of an information disclosure statement under 37 CFR 1.97(d) with the fee set forth in 37 CFR 1.17(p) on 2/16/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
March 13, 2007

A handwritten signature in black ink, appearing to read "M. J. Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER